UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, ex rel. HOWARD ZOUBER, Plaintiff-Relator, v. GENENTECH, INC., ROCHE GROUP, MCKESSON, MCKESSON SPECIALTY HEALTH, and ONMARK, Defendants.	CIVIL ACTION NO. **COMPLAINT** **FILED UNDER SEAL** **PURSUANT TO** **31 U.S.C. § 3730(b)(2)** JURY TRIAL DEMANDED

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On behalf of the United States of America, Plaintiff and Relator Howard Zouber ("Plaintiff" or "Relator") files this *qui tam* Complaint against Defendants Genentech, Inc. ("Genentech" or the "Company"), the Roche Group ("Roche"), McKesson, McKesson Specialty Health ("MSH") and Onmark (collectively, "Defendants") and alleges as follows:

I. INTRODUCTION

1. Relator brings this action on behalf of the United States of America pursuant to the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "False Claims Act" or "FCA") in connection with Defendants' promotion and sale of Genentech's blockbuster ophthalmology drug Lucentis® (*ranibizumab*) ("Lucentis").

2. Pursuant to the FCA, Relator seeks to recover damages and civil penalties arising from false or fraudulent claims that Defendants submitted or caused to be submitted to Medicare Part B, a Federal Government-funded health insurance program.

3. The Relator is a former employee of Genentech. Relator's allegations arise from his knowledge of Defendants' unlawful practices concerning Lucentis, witnessed firsthand over the course of his tenure at Genentech and developed through witness testimony and independent investigation carried out thereafter.

4. As alleged herein, beginning in 2006, Defendants implemented a three-staged illegal kickback scheme through which they created, promoted and leveraged Lucentis' financial benefits over those of competing products, knowing that Lucentis lacked any clinical benefit over any of them.

5. Over the course of their fraudulent scheme, Defendants: (1) promoted the Medicare reimbursement spread between Lucentis and a competing product alongside misleading safety claims to steer physicians away from that product (2006-2008); (2) promoted

the Medicare reimbursement spread between purchasing through Genentech's "Lucentis Direct" program against doing so through distributors (2008-2018); (3) inflated Lucentis' Medicare reimbursement rate by failing to disclose free distribution services that reduced customers' purchasing costs (2008-2018); (4) promoted the Medicare reimbursement spread between purchasing through a Lucentis-dedicated Group Purchasing Organization rather than directly from Medicare (2018-Present); and (5) inflated Lucentis' Medicare reimbursement rate by failing to report administrative and service fee discounts that passed through to customers and lowered their purchase price for the drug (2018-Present).

6. Through means of this scheme, Defendants fueled a perverse incentive among physicians to prescribe Lucentis over clinically more effective and economically more affordable alternatives. Defendants' conduct violated the federal Anti-Kickback statute and the False Claims Act, thereby causing Medicare to pay billions of dollars in reimbursements that it would not have paid had it known of Defendants' illegal scheme.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), which specifically confers jurisdiction to this Court for actions brought under the False Claims Act, 31 U.S.C. §§ 3729 and 3730. This Court also has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1345.

8. Venue is appropriate as to the Defendants in that they may be found, reside and/or transact business in the District of Massachusetts, and/or acts proscribed by 31 U.S.C. § 3729 have been committed by the Defendants in this judicial district. Therefore, venue is proper within the meaning of 28 U.S.C. § 1391(b) and (c), and 31 U.S.C. § 3732(a).

III. PARTIES

A. Qui Tam Relator Howard Zouber

9. Relator Howard Zouber is a citizen of the United States of America and a resident of Illinois. Relator was hired as a Sales Representative with Genentech's Clinical Specialist team at the time Lucentis' launch in 2006. Between 2006 and 2008, Relator was responsible for the promotion and sales of Lucentis to ophthalmologists in Minnesota, North Dakota, and Wisconsin.

10. Between December 2007 and May 2008, Relator completed a marketing rotation as part of Genentech's "Core Lucentis Team" charged with implementing its "Lucentis Direct" promotional program. In August 2008, Genentech awarded Relator its "Commercial Excellence Award" for his contributions to the design and successful implementation of Lucentis Direct. On August 22, 2018 Relator received an email from Jason Bey, Genentech's Associate Director of Commercial Training & Development, stating that Relator "played an integral role in the team's success." Mr. Bey was later promoted to the title of "Regional Sales Director, Lucentis," and held that role through December 2015.

11. As part of the Core Lucentis Team, Relator interacted directly with several Genentech corporate executives who conceived of and were responsible for implementing the central marketing premise detailed herein and carried out throughout the relevant period. The executives with whom Relator interacted during this period included but were not limited to John Snisarenko, who headed the Lucentis franchise, Mike Campbell, the Lucentis National Sales Director and Mr. Snisarenko's direct report, and several Regional Directors who reported to Mr. Campbell.

12. Other members of the Core Lucentis Team included Associate Director of Marketing Dan Tuden, his direct report, Senior Product Manager Jack Gallagher, and Director of Finance Steve Vernay. Relator reported to Mr. Gallagher during his 2007-2008 marketing rotation.

13. In July 2008, Relator was promoted to Manager of Training for Ophthalmology and Asthma, working out of Genentech's San Francisco, California headquarters and reporting to Mr. Bey. While serving in this role in 2009, Relator was awarded the Collaboration Award reserved for members of the Lucentis Direct Team.

14. In June 2010, Messrs. Campbell and Bey promoted Relator to Lucentis Division Sales Manager working out of Chicago, IL. Relator served in this role from June 2010 to July 2012 where he managed a team of six representatives or clinical specialists in Illinois, Wisconsin, Minnesota, Indiana, Iowa, and Kentucky. Relator's employment with Genentech ended in July 2012.

15. As part of his investigation in the years since his departure from Genentech, Relator remained in communication with Mr. Campbell regarding Genentech throughout Mr. Campbell's 2006-2017 tenure at the Company.

16. Relator and Mr. Campbell have also remained in communication with each other, with current Genentech employees, and with Genentech employees who left Genentech after 2017 about developments and statements made within the Company that are germane to the allegations of this Complaint.

17. In December 2017, Relator and Mr. Campbell resumed work together on ophthalmologic drug sales with the pharmaceutical firm Shire plc. In 2019, Mr. Campbell recruited Relator to work at Novartis AG ("Novartis), manufacturer of Lucentis competitor

Beovu® (*brolucizumab*) ("Beovu"). During this period, other Novartis colleagues have communicated information and statements made by Lucentis customers whose business Novartis sought for Beovu.

B. Defendants Genentech, Roche Group, McKesson and Onmark

18. Defendant Roche, headquartered in Basel, Switzerland, develops and manufactures products in both the pharmaceutical and diagnostic markets. Between 2015 and 2018, Roche's pharmaceutical sales revenue in the United States grew from approximately $18 billion to $24 billion.

19. Defendant Genentech, headquartered in San Francisco, California, manufactures and markets products for cancer, eye disease, and other conditions for sale throughout the United States. Genentech is wholly owned by Roche, which acquired Genentech in March 2009. In 2008, the last full year of its existence as an independent company, Genentech's sales exceeded $9.5 billion.

20. Defendant McKesson, headquartered in San Francisco, California, describes itself in marketing materials as a global leader in healthcare supply chain management solutions, retail pharmacy, healthcare technology, community oncology and specialty care. The company reports that it distributes one-third of all pharmaceutical drugs used daily in North America. In 2018, McKesson reported revenue of over $208 billion.

21. McKesson distributes pharmaceutical products for medical specialties such ophthalmology, oncology and other, through its specialty distributor business, Defendant McKesson Specialty Health. As McKesson's specialty drug distributor, MSH's services to ophthalmology practices include distribution, ordering, tracking, and inventory management.

22. Defendant Onmark is a specialty GPO that is owned by and vertically integrated with McKesson. By 2018, Onmark had formed a Lucentis-dedicated Group Purchasing Organization ("Lucentis GPO"). Since 2018, Lucentis prescriptions distributed by MSH through Onmark's Lucentis GPO, have generated more than $1 billion in Medicare Part B reimbursements.

IV. STATUTORY AND REGULATORY BACKGROUND

A. Government Reimbursement of the Products at Issue

1. Lucentis Purchases Under Medicare Part B

23. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*., is a taxpayer-funded Federal health insurance program that pays for covered medical care provided to persons over sixty-five (65) years of age, and to certain others that qualify under the terms and conditions of the Medicare Program. 42 U.S.C. §§ 426, 426-1. Medicare is administered by the CMS, which is part of the Department of Health and Human Services ("HHS").

24. Medicare Part B pays for certain medical treatments and products, including designated injectable drugs administered in physicians' offices and hospital outpatient clinics. *See* 42 U.S.C. §§ 1395k, 1395m, 1395x.

25. Medicare Part B reimburses prescription drug claims through CMS, which contracts with private insurance carriers to administer and pay the claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS.

26. Under Federal health care programs such as Medicare and Medicaid, CMS assigns each drug that qualifies for reimbursement a specific reimbursement code established

under the Healthcare Common Procedure Coding Systems ("HCPCS"). During the relevant period, Lucentis' permanent HCPCS, or "J-Code" code was J2778.

27. Lucentis and its competitors "buy and bill" outpatient prescription drugs. Under this reimbursement regime, physicians typically purchase the drug through distributors and later submit reimbursement claims to Medicare Part B. In addition to buying and billing for the drug, physicians also prescribe and administer the drug, manage and store their practices' drug inventories, and collect the patient's share of reimbursement in the form of copayments or coinsurance.

2. Average Sales Price ("ASP")

28. Since January 2005, Medicare Part B has paid for most covered drugs using the Average Sales Price reimbursement methodology, or "ASP." The ASP is defined as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter, divided by the total number of units of the drug sold by the manufacturer in that same quarter. Social Security Act § 1847A(c), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173.

29. CMS sets a single national payment amount for most Part B-covered prescription drugs at 106% of the volume-weighted ASP. Social Security Act § 1847A(b). Medicare beneficiaries are generally responsible for 20% of this amount in the form of coinsurance.

30. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.

31. Manufacturers report ASPs by national drug codes ("NDC"), which are 11-digit identifiers that indicate the manufacturer, product dosage form, and package size of the drug. Manufacturers must provide CMS with the ASP and volume of sales for each NDC on a quarterly basis, with submissions due 30 days after the close of each quarter.

32. When a manufacturer or repackager submits its quarterly ASP-required information to CMS, the manufacturer's CEO, CFO, or Authorizing Official must certify that:

> the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that the information contained in this submission may be used for Medicare reimbursement purposes.

CMS, Average Sales Price Data, Addendum B, https://www.cms.gov/McrPartBDrugAvgSalesPrice/Downloads/aspdata_addendumb.pdf; *see also* 42 C.F.R.§ 414.904.

B. The Anti-Kickback Statute ("AKS")

33. The Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and can result in the provision of goods and services that are more expensive. To protect the integrity of the Federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The Anti-Kickback Statute was enacted in 1972 "to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the [M]edicare and [M]edicaid programs." Social Security Amendments of 1972, H.R. Rep. No. 92-231 at 107 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

34. In 1977, Congress amended the Anti-Kickback Statute to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. *See* Social Security Amendments of 1972, Pub. L. No. 92-603 § 241(b), (c) (1972), reprinted in 1972 U.S.C.C.A.N. 5370; 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the Anti-Kickback Statute was to combat fraud and abuse in medical settings that "cheats taxpayers who must ultimately bear the financial burden of misuse of funds . . . diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and] erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs." Medicare-Medicaid Anti-Fraud and Abuse Amendments, H.R. Rep. No. 95-393(II) at 7 (1977), reprinted in 1977 U.S.C.C.A.N. 3039, 3047.

35. In 1987, Congress again strengthened the Anti-Kickback Statute to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Anti-Fraud and Abuse Amendments, H.R. Conf. Rep. No. 95-673 at 3 (1977), reprinted in 1977 U.S.C.C.A.N. 3113, 3115; Medicare and Medicaid Patient and Program Protection Act of 1987, S.R. No. 100-109 at 26, reprinted in 1987 U.S.C.C.A.N. 682, 707-08.

36. The Anti-Kickback Statute prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by a federal health care program, which includes any state health program or health program funded in part by the Federal Government. *See* 42 U.S.C. §1320a-7b(b), (f).

37. The statute provides, in pertinent part:

> (b) Illegal remunerations
>
> * * *
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person-
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(2).

38. In addition to criminal penalties, a violation of the Anti-Kickback Statute can also subject the perpetrator to exclusion from participation in federal health care programs (42 U.S.C. § 1320a-7b(b)(7)), civil monetary penalties of $100,000 per violation (42 U.S.C. § 1320a-7a(a)), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose. *Id.*

39. In 1991, the HHS Office of Inspector General ("HHS OIG") promulgated regulations under the AKS. *See* Medicare and State Health Care Programs: Fraud & Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,958 (July 29, 1991) ("HHS OIG Anti-Kickback Provisions").

40. The Anti-Kickback Statute not only prohibits outright bribes and rebate schemes, but also prohibits any payment or other remuneration to a physician or other person which has as one of its purposes the inducement to purchase, administer and/or write prescriptions for one

manufacturer's pharmaceutical products or the inducement to influence or recommend the prescribing of the product. The AKS remuneration provision is very broad in plain language and in purpose: it prohibits "offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1320a-7b(b)(2). The AKS further defines "remuneration" to include "transfers of items or services for free or for other than fair market value." *Id.* § 1320a-7a(i)(6).

41. Underscoring the breadth of the statutory definition, the HHS OIG Anti-Kickback Provisions, 56 Fed. Reg 35,952, 35,958 (July 29, 1991), broadly define the term "remuneration" as "anything of value in any form . . . whatsoever." *See also* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg 23,731, 23,734 (May 5, 2003) (the "OIG Guidelines") (AKS addresses the offer or payment of "anything of value").

42. Medicare requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute (discussed *infra*) and with other federal laws governing the provision of health care services in the United States. In other words, if a provider tells CMS or its agent that it provided services in violation of the Anti-Kickback Statute or another relevant law, CMS will not pay the claim.

43. For example, physicians and hospitals enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which the hospitals and physicians may not seek reimbursement from Federal Health Care Programs, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and

the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

Form CMS-855A at 48; *see also* Form CMS-855I at 23 (effective 2001). In addition, the claims themselves as submitted contain a similar certification. *See, e.g.*, Form CMS-1500.

44. When a provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the Anti-Kickback Statue.

1. Defendants' Promotional Practices Implicating the AKS

45. Concern about improper drug marketing practices further prompted the HHS OIG to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback Statute. *See* Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994) ("Special Fraud Alert: Prescription Drug Marketing Schemes.").

46. Then, on June 11, 2001, the HHS OIG published a solicitation notice seeking information and recommendations for developing compliance program guidance for the pharmaceutical industry. *See* Solicitation of Information and Recommendations for Developing a Compliance Program Guidance for the Pharmaceutical Industry, 66 Fed. Reg. 31,246 (June 11, 2001). The HHS OIG's resulting draft guidance was published for notice and comment in October 2002. *See* Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 67 Fed. Reg. 62,057 (Oct. 3, 2002). In May 2003, the HHS OIG published further guidance on marketing practices which may constitute kickbacks and other illegal remuneration affecting federal health care programs. OIG Guidelines, 68 Fed. Reg. 23,731 (May 5, 2003).

a. Marketing the Spread

47. Among other things, the OIG's Guidance cautions against engaging in "marketing the spread": "[t]o the extent that a manufacturer controls the 'spread,' it controls a customer's profit." It further observes that "[t]he conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute." OIG Guidelines, 68 Fed. Reg. 23,731, 23,736-37 (May 5, 2003).

48. The "spread" refers to the difference in value between what a provider pays for a drug and the reimbursement that the provider receives (usually from government or private health insurance) for a drug to be administered to a beneficiary. The greater the difference between provider cost and program reimbursement, the greater the "spread"—and the greater the provider profit.

49. In 2003, when the OIG Guidance was published, under the Medicare Program, and other federal and state health care programs, prescription drug reimbursement amounts generally used the AWP as a benchmark price to determine reimbursement. The AWP for a prescription drug is a self-reported price, i.e., it is not independently and objectively determined. Rather, manufacturers provide AWP data to publications such as First Data Bank, which publish the information without scrutiny.

50. After the OIG Guidelines were issued, CMS replaced AWP with ASP plus 6% (adjusted for sequestration), effective January 1, 2005, as the basis for Medicare drug reimbursement. State Medicaid Programs use varying reimbursement methodologies, including AWP, ASP, Best Price, Average Manufacturer Price, and Wholesale Acquisition Cost.

Regardless of what methodology is used, marketing the spread constitutes illegal remuneration and violates the AKS.

51. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under a Government Health Care Program, including Medicare and the state Medicaid programs. Moreover, compliance with the Anti-Kickback Statute is a condition of payment for drug claims administered by physicians for which Medicare or Medicaid or other Government Health Care Program reimbursement is sought.

b. Manipulation of Average Sales Price

52. Where a defendant has "intentionally failed to report . . . 'off-invoice' rebates in order to keep secret the 'profit spread' between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread," an FCA violation results. *U.S. Duxbury v. Ortho Biotech Pro*, 579 F.3d 13, 31 (1st Cir. 2009).

53. Marketing the spread combined with false ASP reporting establishes "unlawful intent" under the AKS. *United States v. Amgen, Inc.*, 812 F. Supp. 2d 39, 70 (D. Mass. 2011) (citing OIG Guidelines, 68 Fed. Reg. 23,731, 23,736 (May 5, 2003)).

2. AKS Safe Harbors Implicating Defendants' Discounting Arrangements

a. Discount Safe Harbor

54. The AKS's Discount Safe Harbor protects "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(A).

55. The Discount Safe Harbor's requirements are further enumerated at 42 C.F.R. § 1001.952(h). While the safe harbor protects certain valid discounts, protection does not include "[s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology." *See* 42 C.F.R. § 1001.952(h)(5)(ii); Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,530 (Nov. 19, 1999) (Final Rule).

b. GPO Administrative Fee Safe Harbor

56. 21 C.F.R. § 203.3 defines "Group Purchasing Organization" ("GPO") as follows:

> § 203.3 Definitions.
>
> (o) Group purchasing organization means any entity established, maintained, and operated for the purchase of prescription drugs for distribution exclusively to its members with such membership consisting solely of hospitals and health care entities bound by written contract with the entity.

57. GPOs are buying consortiums or associations of hospitals, clinics, doctors, and healthcare organizations that are designed to leverage the aggregate purchasing power of members and thereby increase their ability to negotiate contract terms with various suppliers of drugs, medical devices, and other goods and services.

58. GPOs negotiate such aggregate purchases, but do not typically purchase the products themselves from manufacturers or suppliers. Rather, GPO member providers make the actual purchases once a GPO-negotiated contract is in place. *See, e.g.*, HHS OIG Report, Review of Revenue from Vendors at Three Group Purchasing Organizations and Their Members (A-05-03-00074), (Jan. 19, 2005), http://oig.hhs.gov/oas/reports/region5/50300074.pdf.

59. While GPOs act as agents for and are paid by their members, their primary source of compensation is "administrative" or "service" fees received from the vendors or suppliers. Vendors and suppliers pay these fees to GPOs in exchange for certain administrative services and the ability to sell through the GPO to its members. *See* HHS OIG Report, *supra*. Administrative fees are calculated as a small percentage, generally less than 3%, of the revenue generated under the GPO contract. *See id.*

60. Regulations promulgated by the HHS OIG provide limited AKS "safe harbor" protection of such administrative fees by certain imposing standards for the written agreement between the GPO and its members. *See* 42 C.F.R. § 1001.952. A GPO may invoke the "safe harbor" only under the following conditions:

> (1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following -
>
> > (i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.
> >
> > (ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).
>
> (2) Where the entity which receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity. Note that for purposes of paragraph (j) of this section, the term group purchasing organization (GPO) means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

42 C.F.R. § 1001.952(j)(1)-(2).

61. Amounts paid under a federal healthcare program by manufacturers to a GPO are subject to safe harbor protection under the AKS. GPOs are allowed to collect contract administrative fees from manufacturers and other vendors that could otherwise be considered unlawful, provided that they have written agreements with their customers either stating that fees are to be 3 percent or less of the purchase price, or specifying the amount or maximum amount that each vendor will pay. 42 C.F.R. § 1001.952(j)(1). GPOs must also disclose in writing to each customer, at least annually, the amount received from each vendor with respect to purchases made by or on behalf of the customer. *Id.* at § 1001.952(j)(2).

62. Parties to a GPO arrangement may not obtain safe harbor protection by entering into a contract that formally complies with the written agreement requirement of a safe harbor and appears, on paper, to meet all of the other safe harbor requirements, but that does not reflect the actual arrangement between the parties. *See, e.g.*, 42 C.F.R. § 414.802 (fees must be "bona fide" to be excluded from ASP calculations).

63. Administrative or service fees charged by GPOs and paid to them by manufacturers and other vendors are material to Medicare's calculation of the ASP at which a covered drug is reimbursed.

c. Bona Fide Services Fee Safe Harbor

64. While manufacturers must deduct price concessions when calculating ASP, "bona fide services fees" paid to distributors and GPOs are not considered price concessions and therefore not included in this calculation. 42 C.F.R. § 414.804(a)(2).

65. For reporting periods beginning January 1, 2007 and thereafter, manufacturers have been required to use the definition of bona fide service fees specified in 42 C.F.R. § 414.802. *See* 42 C.F.R.§ 414.802 (defining bona fide service fees as "fees paid by a

manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.").

66. Distributors and GPOs like Defendants McKesson and Onmark are among the entities to which manufacturers may pay bona fide service fees. Thus, bona fide service fees include, among other things, fees paid to wholesalers, distributors and GPOs "includ[ing] . . . distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements." *See* Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5,170, 5,347 (Feb. 1, 2016).

67. "If a manufacturer has an agreement with the GPO that any of these fees are passed on to the GPO's members or customers, they would be considered price concessions and not excluded as bona fide service fees. When there is evidence or knowledge that the fee or other price concession is passed on to the GPO's member or customers (for example, the contract between the manufacturer and GPO or other service provider may contain a provision that indicates the fee be used by the provider to further discount the price paid by the wholesaler or retail community pharmacy), the manufacturer must account for such fee or price concession." *Id.* at 5,181.

68. In general, a bona fide service fee is a fee that a manufacturer pays to an entity to perform a service that the manufacturer would otherwise perform itself.

69. When certifying to the accuracy of their ASP calculations, if a manufacturer has determined that a fee paid meets the other elements of the definition of bona fide service fee, then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that

the fee paid is not passed on to a client or customer of any entity. Physician Fee Schedule (PFS), 71 Fed. Reg. 69,624, 69,669 (Dec. 1, 2006) (final rule); Medicaid Program, Covered Outpatient Drugs, 81 Fed. Reg. 5,170, 5,181 (Feb. 1, 2016).

70. In the absence of specific statutory or regulatory guidance to the contrary, Manufacturers may make "reasonable assumptions" in their calculation of ASP, which should be submitted along with the ASP data and accompanying certifications. *U.S. v. Amgen, Inc.,* 812 F. Supp. 2d 39, 72 n.24 (D. Mass. 2011)" *See U.S. ex rel. Streck v. Bristol-Myers Squibb Co.*, Civ. No. 13-7547, at *25 (E.D. Pa. Nov. 29, 2018) (denying bona fide safe harbor protection in an FCA case where "even assuming the ambiguity of the underlying statutes and rules governing the calculation of AMP and the objective reasonableness of BMS's interpretation of them, the motion to dismiss fails because BMS was warned away from its interpretation").

C. THE FALSE CLAIMS ACT

71. The FCA holds liable anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" by the United States, 31 U.S.C. § 3729(a)(1)(A), or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* at § 3729(a)(1)(B). Those who violate the FCA are liable for civil penalties not less than $10,781.40 and not more than $21,562.80 per violation, three times the damages sustained by the Government and litigation costs. *Id.* at § 3729(a)(1).

72. The FCA provides that any person having information about false or fraudulent claims or records presented to the United States may bring an action for both herself and the Government and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to enable the

Government to (a) conduct its own investigation without the defendant's knowledge and (b) determine whether to join the action.

73. Federal law makes clear that violation of the Anti-Kickback Statute can support FCA liability. For example, the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(f)(l), 124 Stat. 119 (2010) ("PPACA"), which became law on March 23, 2010, provides: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." In other words, pursuant to the PPACA, claims for items or services billed to government-funded healthcare programs (including Medicare) "resulting from" a violation of the anti-kickback statute are, without question, "false or fraudulent claims" under the FCA.

74. Under federal law, proof that a defendant knew of and specifically intended to violate the AKS is not required; rather, proof that the defendant intended to perform the actions that violated the AKS gives rise to a violation is required. *See also* PPACA § 6402(f)(2) ("a person need not have actual knowledge of this section or specific intent to commit a violation" of the AKS in order to be found guilty of a "willful violation").

75. At all times relevant to this Complaint, compliance with the AKS has been a condition to participation for a health care provider under Medicare and other Government Health Care Programs. Further, compliance with the AKS is a condition of payment for claims made to Medicare and other Government Health Care Programs for reimbursement.

76. Accordingly, violations of the AKS are *per se* material under the FCA, *Guilfoile v. Shields*, 913 F.3d 178, 189 (1st Cir. 2019), and all government reimbursement claims for products tainted by a defendant's kickbacks are false or fraudulent in violation of the FCA. *U.S.*

ex Rel. Hutcheson v. Blackstone Medical, 647 F.3d 377, 394 (1st Cir. 2011). The AKS covers all Government Health Care Programs, including the Medicare Part B claims at issue in this action.

V. FACTUAL BACKGROUND

A. Lucentis and Its Competitors in the Wet AMD Market

1. Neovascular Age-Related Macular Degeneration ("wet AMD")

77. Age-related macular degeneration ("AMD") is the leading cause of vision impairment among people aged 50 or over in the United States.[1] The disease is characterized by slow, progressive vision loss and can ultimately cause patients to become legally blind.

78. Relator's allegations concern the less common but more serious variation of AMD, referred to as Neovascular AMD ("nAMD") or "wet AMD." Wet AMD causes injury to the macula, which is located near the center of the retina. It occurs when blood vessels under the retina grow abnormally, causing scarring and deterioration of the macula and accelerating vision loss. This activity is caused by vascular endothelial growth factor ("VEGF"), which promotes the growth of weak blood vessels that leak fluids into the macula.

79. The most common treatments for the condition are anti-VEGF pharmaceutical drugs, which block the detrimental effects of VEGF. Prior to development of VEGF inhibitors, more than 90% of patients diagnosed with wet AMD became legally blind within one year of treatment. VEGF inhibitors have dramatically improved treatment outcomes.

80. These clinical advancements notwithstanding, "[b]y 2020, it is projected that nearly three million people will experience visual impairment from neovascular age-related macular degeneration." DW Hutton, et al., Switching to Less-Expensive Blindness Drug Could

[1] *See Age-Related Macular Degeneration*, National Eye Institute (last updated Aug. 2, 2019), https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/age-related-macular-degeneration.

Save Medicare Part B $18 Billion Over A Ten-Year Period, 2 (June 1, 2015) (author manuscript) (on file with NIH Public Access).

2. Lucentis

81. Genentech developed and received approval for its VEGF inhibitor drug Lucentis (*ranibizumab*) to treat wet AMD in July 2006.[2] The Roche Group holds the sole rights to sales of Lucentis in the United States.

82. For its Wet AMD indication, physicians typically administer Lucentis 0.5 mg (0.05 mL) by intravitreal injection once per month, priced at $1,950 per injection.

83. In the decade between 2007 and 2017, Medicare Part B has reimbursed more than $11 billion in Lucentis prescriptions. In 2018, Lucentis' U.S. sales increased 18% to reach $1.67 billion. Lucentis' U.S. sales in the first three quarters of 2019 reached $1.38 billion, a 9% increase over the prior year.

3. Avastin[3]

84. Genentech's Avastin (*bevacizumab*) is the world's fifth highest-grossing cancer drug, with 2018 revenues estimated at $6.8 billion.[4] *See* Alex Philippidis, *Top 10 Best Selling Cancer Drugs of 2018*, GEN: Genetic Engineering and Biotechnology News (April 22, 2019), https://www.genengnews.com/a-lists/top-10-best-selling-cancer-drugs-of-2018/.

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[2] Between 2010 and 2017, Lucentis later gained indications for several other eye disorders, including Macular Edema Following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy in patients with DME, Myopic Choroidal Neovascularization, and Diabetic Retinopathy.

[3] Before the FDA approval and launch of Lucentis in 2006, the only FDA-approved drugs for treatment of nAMD were Visudyn (approved in 2000) and Macugen (approved in 2004). Both of these drugs offered only limited efficacy for most patients, however, and are viewed in the medical community to be inferior to anti-VEGF drugs like Lucentis.

[4] Avastin was approved for metastatic colorectal cancer in February 2004 and later gained several other indications, including locally advanced, recurrent or metastatic non-small cell lung cancer, treatment of glioblastoma multiforme, and treatment of metastatic renal cell carcinoma.

85. Avastin is derived from the same biological material that Genentech later used to develop Lucentis, resulting in both having a similar (if not identical) anti-VEGF mechanism of action. Both drugs are produced in the same manufacturing plant, with vials alternately marked with the two different product names on the same line.

86. While it has never been FDA approved for any ophthalmologic use, Avastin is widely viewed in the medical community as a safe and effective VEGF inhibitor for use in treating wet AMD. This support for Avastin's off-label use has resulted in the drug's receiving *de facto* Medicare approval, insofar as, over time, Medicare carriers nationwide have opted to provide Medicare reimbursement for the off-label use.

87. Avastin's price tag is comparable to that of Lucentis when used for colon cancer but is priced at $50 per intravitreal injection for its off-label wet AMD indication because it is dosed at a small fraction of that for Avastin's on-label oncology indications.

88. Avastin is shipped from the manufacturer to specialty pharmacies that repackage the drug's much larger oncology doses into smaller doses for the eye, and then deliver the wet AMD injections to doctors' offices.

89. Avastin has held significant market share in the Anti-VEGF market throughout the relevant period despite its off-label status.

4. Eylea

90. On November 18, 2011, Regeneron received a wet AMD indication for its VEGF inhibitor Eylea (*afilbercept*) ("Eylea").[5]

91. Eylea is priced at $1,850 per intravitreal injection to treat wet AMD. In contrast to Lucentis' twelve injection per year regimen, Eylea requires eight injections annually,

[5] Eylea was subsequently approved for DME and diabetic retinopathy in patients with DME in 2014 and 2015, respectively.

primarily in 8-week intervals. Because of this less frequent dosing, Eylea costs between $8,000 and $16,000 less than Lucentis per year per patient.

92. Many wet AMD patients prefer Eylea to Lucentis due both to the fewer injections and the lower co-pay amount required.

5. Beovu

93. Novartis' VEGF inhibitor Beovu (*brolucizumab*) received an indication for the treatment of wet AMD on October 8, 2019.

94. Beovu is priced identically to Eylea at $1,850 per intravitreal injection. In contrast to Eylea's 8-injection regimen, Beovu patients receive 12 injections, primarily in 12-week intervals.

95. Analysts have suggested that Novartis' Beovu has the potential to grow quickly to blockbuster sales levels, reaching as high as $4.38 billion by 2021.[6]

B. Genentech Aggressively Positions Lucentis to Secure and Maintain Blockbuster Sales in the Wet AMD Market

1. Genentech Blocks a Wet AMD Approval Path for Avastin

96. Since 2003, the medical community has aggressively lobbied Genentech to conduct the necessary trials to secure Avastin's FDA approval for wet AMD.

97. By the time Lucentis first became available on the market, Avastin had already emerged as a powerful tool to combat wet AMD, despite its lack of an indication for the condition.

98. This is because, between July 2005 and Lucentis' 2006 launch, researchers accumulated a vast clinical experience of hundreds of thousands of Avastin injections, forming

[6] *See, e.g.*, Angus Liu, *Regeneron touts Eylea countermeasure as Novartis goes aggressive with Beovu launch*, FiercePharma (Nov. 5, 2019) https://www.fiercepharma.com/pharma/regeneron-touts-eylea-countermeasures-as-novartis-goes-aggressive-beovu-launch.

the basis of a widespread consensus within the medical community that off-label use of Avastin was safe and effective for most wet AMD patients. Ophthalmologists nationwide swiftly began prescribing Avastin off-label in response.

99. In 2008, Genentech went so far as to halt sales of Avastin to compounding pharmacies that had been dividing Avastin into the smaller quantities needed for treating the eye. While, typically, any specialty pharmacy can carry out this practice as long as they are accredited and licensed to do so, Genentech blocked such pharmacies from doing so for Avastin in 2008. Thereafter, pharmacies seeking to order Avastin were required to have a physician on staff, or the product had to be ordered by a physician and shipped to the pharmacy. This strategy was a transparent attempt to restrict the off-label use of Avastin rather than to raise any legitimate concerns about Avastin's safety profile.

100. Genentech was eventually forced to reverse course after receiving strong opposition from ophthalmologists, compounding pharmacists, and patient advocates. During a 2007 AAO meeting, one spokesman for the International Academy of Compounding Pharmacists, Joshua Wenderoff, publicly questioned whether Genentech's decision was genuinely based on safety concerns. "We believe Genentech is putting profit ahead of patients," Wenderoff said at the conference.

101. In February 2008, the National Eye Institute ("NEI") of the National Institutes of Health ("NIH") announced the start of a widely anticipated multicenter clinical trial to compare the relative safety and effectiveness of Lucentis and Avastin to treat AMD. This study was referred to as the Comparison of AMD Treatment Trials or "CATT" study.

102. Notwithstanding the two drugs' interchangeable nature, Genentech disregarded the medical community's support for Avastin in the years and months leading up to Lucentis'

launch. But Avastin's legitimacy as an appropriate standard of care for nAMD treatment would only strengthen over time, despite Genentech's best efforts.

103. Seeking to bypass Genentech, the American Academy of Ophthalmology, fueled by an outspoken group of ophthalmologists, turned directly to local Medicare carriers, who were authorized to make local coverage determinations on an ad hoc basis. Recognizing Avastin's combination of efficacy and affordability, several Medicare carriers took the unusual step of providing coverage for the off-label use of Avastin to treat nAMD.

104. In April 2012, the official CATT results were in: Avastin and Lucentis were equivalent in treating AMD and had comparable safety risks. The CATT study found that serious adverse events (SAEs) occurred at a 40% rate for patients receiving Avastin and occurred at a 32% rate for patients receiving Lucentis. Although there was a higher rate of SAEs for Avastin, the study showed that those SAEs were across many different conditions and were not associated with Avastin in cancer clinical trials.

105. Avastin's appeal to physicians and payers as Lucentis' far more affordable substitute represented an existential threat to Lucentis' promise as Genentech's leading blockbuster product. Thus, even before the first Lucentis prescription was written, Genentech had a powerful incentive to steer physicians away from Avastin as part of its promotional campaign for Lucentis.

2. Genentech Radically Inflates Lucentis' Sales Price

106. Genentech's original price for Lucentis was $4,000 per vial, a full eighty times the price of Avastin, which at the time was the only other VEGF product on the market that could pose any clinical threat to Lucentis.

107. In response to objections by Avastin supporters within the medical community, however, Genentech was forced to reduce the price of Lucentis from $4,000 to $2,000 per injection soon after the launch. Ultimately, Genentech settled on $1,950 per injection, leaving Lucentis with a 94% profit margin. Genentech's total manufacturing costs, including marketing, sales, packaging, shipping, and manufacturing amounted to between only $150-$180 per vial.

108. Lucentis was priced in this way because Genentech far preferred Lucentis to Avastin for wet AMD, notwithstanding the latter's blockbuster performance in the oncology market, and notwithstanding the medical community's clinical acceptance of its off-label use to treat wet AMD.

109. While Genentech publicly stated otherwise, Relator is aware that it preferred Lucentis for wet AMD for economic rather than clinical reasons. Avastin's very low pricing for AMD is consistent with its very high pricing for its on-label oncology indications, because the latter are administered in doses some forty times larger than Avastin's dosing in ophthalmology.

110. Due to the massive pricing disparity between Lucentis and Avastin's use for wet AMD, Genentech stood to profit far more from sales of the former in the AMD market.

111. Lucentis' exorbitant price tag and its ensuing effect on government healthcare programs has not escaped the Government's notice. In September 2011, the Office of the Inspector General ("OIG") conducted a review of Medicare Part B Avastin and Lucentis nAMD treatments. The OIG found that:

> [b]ased on statistical sampling, we estimated that for wet AMD treatments, Medicare Part B paid physicians $40 million for 936,382 Avastin treatments and $1.1 billion for 696,927 Lucentis treatments furnished during the period of our review. We calculated that if Medicare reimbursement for all beneficiaries treated with Avastin or Lucentis for wet AMD had been paid at the Avastin rate during calendar years (CY) 2008 and 2009, Medicare Part B would have saved approximately $1.1 billion and beneficiaries would have saved approximately $275 million in copayments.

Daniel R. Levinson, *Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration*, OIG, ii (Sept. 2011), https://oig.hhs.gov/oas/reports/region10/11000514.pdf.

112. In April of 2014, the Centers for Medicare and Medicaid Services ("CMS") released billing data for physician services. The data set revealed payments to over 880,000 health care providers who collectively received $77 billion in 2012 under the Medicare Part B fee-for-service program. *Id.* at 2-3.

113. The data further revealed that Dr. Salomon Melgen, a South Florida ophthalmologist who had received the staggering sum of $21 million in Medicare reimbursements in 2012, held the dubious distinction of being the physician whom Medicare had paid the most that year. Dr. Melgen's most common Medicare reimbursements had come from Lucentis. Dr. Melgen was ultimately indicted for Medicare fraud, including medically unnecessary claims; in 2015 and in 2017, a jury returned a guilty verdict on 67 of the 76 counts in the indictment.[7]

VI. GENENTECH'S ILLEGAL KICKBACK SCHEME

A. Defendants Developed and Adapted Their Business Model to Financially Induce Lucentis Purchases

1. Lucentis' Clinical and Pricing Profiles Inherently Required Defendants to Promote Its Financial Rather Than Clinical Advantages

114. Genentech opted to compete with other wet AMD products through financial inducement rather than scientific innovation or other forms of product improvement. It chose to do so not only due to Lucentis' lack of a clinical advantage, discussed above, but also because

[7] *See* United States v Salomon E. Melgen, *The United States Attorney's Office for the Southern District of Florida* (updated Jan. 9, 2018), https://www.justice.gov/usao-sdfl/united-states-v-salomon-e-melgen.

Lucentis' inflated pricing created accounting problems that contributed to many providers choosing Avastin.

115. Ophthalmology practices typically purchase buy and bill drugs like Lucentis and its competitors from a specialty distributor. Some distributors in turn make high volume credit card purchasing available to customers upon request. However, while providers are not required to secure credit lines through their own collateral when making such purchases through distributors, standard practice in the industry is for distributors to invoice customers for the credit card company's transaction fees.

116. Accordingly, Lucentis' $1,950 per vial price meant that providers could not maintain an adequate inventory of vials for their patients unless they charged hundreds of thousands of dollars on credit cards monthly.

117. This created a strong disincentive for physicians to prescribe Lucentis over Avastin; to do so would require them to choose between laying out tens or hundreds of thousands of dollars for Lucentis purchases while awaiting Medicare reimbursement for the purchases, or paying thousands or tens of thousands of dollars in transaction fees.

118. During Lucentis' first six to seven months on the market, Genentech was able to delay the effect of this inconvenience on its customers, which posed a threat to the entire franchise. As is customary upon FDA approval, Lucentis was assigned a temporary "J-Code" for billing under Medicare Part B. During this period, the timing of Medicare reimbursement is uncertain as the market acclimates itself to a new product. Therefore, Genentech temporarily paid distributors to wait 180-days before collecting on their invoices so that physicians would not be required to pay for Lucentis before Medicare reimbursed them.

119. This practice changed abruptly in approximately January 2008, when CMS assigned Lucentis its permanent J-code, and guaranteed reimbursement within 30-60 days. Genentech removed the 180-day billing terms for which it had been paying the distributors, immediately following which distributors began requiring payment within 30 days, before Medicare Part B reimbursed for the drug.

120. Distributors further required that, if the physicians wanted to use credit cards, they would have to incur the approximately 2% transaction fee the credit card companies charge the distributors for card purchases.

121. This created an enormous financial burden for physicians, who would find it nearly impossible to manage the cash flow with a $1,950 per injection drug and did not want to incorporate credit card transaction fees into their business expenses.

122. These accounting issues affected the full range of ophthalmology practices, from the larger practices, whose monthly spending could reach the seven figures, to very small practices. Monthly Lucentis purchases for even two or three physician ophthalmology practices routinely numbered 200 or more injections per month, at a total cost of $400,000.

123. While purchasing similar volumes of inventory was routine for these practices regardless of what nAMD drug was prescribed, advancing these large sums while awaiting Medicare reimbursement and paying credit card fees on purchases of that size were a near impossibility for many practices, and unacceptable to many who could manage.

2. Genentech Encoded Reimbursement into the DNA of Lucentis' Promotional Message

124. Lucentis' clinical equivalence to Avastin and accounting challenges required Genentech to pursue an unconventional marketing strategy that capitalized on the potential

financial rewards that physicians could earn off of the large dollar amount that Medicare paid for each vial.

125. Relator's rotation at Genentech's San Francisco headquarters during the planning stages of Defendants' fraudulent kickback scheme placed him in plain view of Defendants' organization of the entire Lucentis sales force around this marketing strategy. During this period Relator worked directly with many of the key Genentech executives who led the strategy, including Vice President of Ophthalmology Franchise John Snisarenko, National Sales Director Mike Campbell, and Regional Directors responsible for territories nationwide.

126. Soon after launch, Genentech held a launch meeting for its Lucentis sales representatives at headquarters. During the meeting, Genentech executives led by Business Unit Head Quinton Oswald, Mr. Snisarenko, and Regional Sales Directors Joni Fausett, Jason Bey, and Mike Miller, emphasized the lucrative revenue opportunities presented by what they described as Lucentis' "100% mark-up" and "$180 cost of goods."

127. During this period, Relator attended a dinner in San Francisco with Messrs. Snisarenko, Campbell and Miller, at which the group discussed the central role that Lucentis' unique pricing could contribute to the Company's promotional campaign for the product.

128. Mr. Snisarenko explained that, from the customers' perspective, a more expensive drug would result in a larger return from Medicare than a less expensive one under the buy and bill model. Mr. Snisarenko also described how Genentech would able to secure higher profits from Lucentis than from its other products through its abnormally wide profit margins.

129. Relator was also privy to discussions of "Project Direct" with senior Lucentis franchise leadership during this period, including Messrs. Tuden, Gallagher and Campbell. Project Direct was the genesis of what ultimately became Lucentis Direct, Genentech's in-house

direct distribution model containing structural incentives for customers to convert to and maximize purchases of the product.

130. Lucentis Direct's blueprint is reflected in an internal August 2007 business update to Genentech's "Northwest Division" sales force that, among other things: (i) describes customer concerns about reimbursement rates and distribution fees for the products at issue; (ii) targets Avastin as a revenue threat to be combated through changes in marketing practices; and (iii) introduces the concept of creating an alternative distribution channel to reward customers for purchases of Lucentis.

131. As detailed herein, Genentech later would adapt Lucentis Direct specifically to address competition from Eylea and Beovu.

B. Stage 1: Genentech Promotes the Profitability of Prescribing Lucentis Over Clinically Equivalent Avastin (2006-2008)

132. During Lucentis' first years on the market, Genentech's primary marketing objective was to incentivize existing Avastin prescribers to convert to Lucentis and to preserve those incentives for existing and new Lucentis prescribers.

133. While some dissenters within Genentech's leadership sought to maintain focus on the clinical benefits of Lucentis over those of Avastin, this minority view did not prevail. The minority view, held by the Medical Science Liaison Team, was especially unpopular because ophthalmologists had quickly come to see neither a clinical benefit nor a net financial benefit to purchasing Lucentis over Avastin.

134. Clinically, Genentech capitalized on the fact that many physicians were reluctant to prescribe Avastin for nAMD over Lucentis in the absence of a definitive clinical trial comparing the two products. Genentech found that, as long as it continued to thwart the medical

community's efforts to secure an FDA-approved nAMD indication for Avastin, the Company could steer physicians towards Lucentis through false claims of its purportedly superior safety profile over Avastin.

135. Even more than Lucentis' unremarkable clinical performance against Avastin, ophthalmologists objected to the burden that Lucentis' pricing placed on their practices. While ophthalmology practices were familiar with Medicare Part B's requirement that they submit reimbursement claims only after the drug has been purchased and administered, many had not previously purchased drugs as expensive as Lucentis. For Medicare patients being treated with Lucentis, physicians were required to advance $1,950 for each patient visit and were repaid after the treatment was administered and the claim submitted to Medicare.

136. In its August 2007 business update, Genentech's Northwest Division includes "[r]eimbursement (underpayments & payment delays)" among "common growth obstacles across the Division" and describes reimbursement as a "significant challenge to Lucentis."

137. Relatedly, although Medicare's ASP + 6% markup ultimately netted physicians $117 to Avastin's $10 per injection, Lucentis' pricing required physicians to charge Medicare patients lacking supplemental coverage a more than $400 Lucentis co-pay in order to be made whole. Many physicians were also unwilling or reluctant to subject their often elderly and sometimes otherwise vulnerable patients to this financial burden, particularly given that Avastin's co-pay was approximately $1.00. With patients requiring six to twelve injections annually, sometimes in both eyes, Lucentis could cost a patient over $10,000 per year in copays alone. Eventually, many physicians chose to bill patients out of pocket for the full cost of Avastin if they did not have strong enough coverage for any alternative therapy because it was still a fraction of the co-pay for Lucentis and other competitors.

138. Responding to these objections, Genentech during the first stage of their illegal promotional scheme: (1) opted to make false superiority claims regarding Lucentis' safety profile, rather than invest resources into the development of a clinically superior product; and (2) chose to promote the more lucrative Medicare Part B reimbursement revenue customers would receive were they to buy Lucentis over Avastin due to the former's much higher price.

139. To carry out their two-pronged attack, Genentech created two separate sales forces: the Clinical Specialists and the Field Reimbursement Management Team.

1. Genentech's Sham "Clinical Specialist" Team Promotes Unsubstantiated Safety Claims Regarding Avastin

140. Led by Lucentis Head of Sales Anne Fields, Genentech's Clinical Specialists ("CS") were a team of 48 sales representatives across the country whose official purpose was to provide clinical information about Lucentis to customers to inform their prescribing decisions. In practice, however, CS's primary activity was to promote false and unsubstantiated claims regarding Avastin's safety profile when used off-label to treat wet AMD.

141. Avastin's broad and growing support within the ophthalmology community and local Medicare carriers' willingness to reimburse off-label prescriptions of the drug for nAMD posed a grave financial threat to Genentech, which had worked diligently to deny Avastin as a legitimate standard of care for nAMD. In response, Genentech developed two false safety narratives for its CS sales force to communicate to potential Lucentis customers.

142. First, CS told physicians that off-label use of Avastin risked causing strokes in patients because, unlike Lucentis, Avastin is composed of a larger molecule and full-length antibody that has the potential to remain undissolved in the blood after use.

143. During conference calls with other members of the CS team while he was a member, Relator was instructed to convey to physicians that, according to "best practices," "on-label is always safer than off-label, especially with a drug that has shown to cause strokes." This tactic was especially effective while selling Lucentis to small single-office doctors, whose entire practices would be at risk were a patient to become severely injured following an injection.

144. Second, Genentech focused physicians on an alleged contamination risk involved in the re-packaging of Avastin for ophthalmologic use. Because Avastin dosing for oncology was much larger than that for ophthalmology, Avastin customers are required to use re-packagers in order to create proper dosing units. Pointing to what it claimed to be a manufacturing flaw inherent in Avastin's off-label use, Genentech misleadingly exploited an outbreak of Endophthalmitis at a U.S. Department of Veterans' Affairs hospital as an opportunity to claim that Lucentis is safer to use than Avastin.

145. Endophthalmitis is an inflammation of the interior of the eye that can cause vision impairment or even severe eye damage. Genentech claimed that the outbreak was caused by re-packaging that occurred at the VA hospital even after the Company became aware that it had resulted not from the Avastin itself, but from contaminated syringes that the compounding pharmacy had used to administer the product.

146. Ultimately, Lucentis' astronomical pricing would contribute to the failure of this scare tactic in more ways than Genentech may have expected. Rather than switch from Avastin to Lucentis, the VA opted to purchase and inject the smallest vial size of Avastin, and then discard the remainder rather than spend five times as much money for one syringe of Lucentis.

147. While Genentech officials publicly stated that they would not interfere with a physician's choice to prescribe Avastin for ophthalmic uses, unofficially they went to great lengths to peddle their false safety messages to get physicians to prescribe Lucentis instead.

2. Genentech's Field Reimbursement Management Team ("FRM") Marketed Lucentis' Medicare Part B Reimbursement Spread Over Avastin's

148. Defendants' FRM team consisted of over twenty reimbursement specialists throughout the country who were officially tasked with providing standard reimbursement assistance to Lucentis enrollees, with a particular focus on larger and high-volume accounts.

149. Genentech trained FRMs to sell against the use of Avastin for wet AMD by illustrating how much profit physicians could make by choosing Lucentis over Avastin.

150. While the FRM team was not officially part of the sales team, its members were routinely included on sales calls and attended lunches with potential purchasers, where they could speak about reimbursements while the CS representative purportedly focused on the sharing of clinical information.

151. Genentech's talking points for the FRM team included a rhetorical question asking why ophthalmologists would choose to prescribe Avastin, an off-label drug that was neither reliably safe nor reliably reimbursable, over Lucentis, an FDA-approved drug for which Medicare reimbursement is guaranteed, and at a much higher margin.

152. The following is an example of a marketing pitch that FRM team members would present directly to physicians to emphasize the financial gain that their practices could earn from Lucentis' Medicare Part B reimbursement rates.

	Doctor 1: Avastin only	**Doctor 2: Lucentis only**
Injections per month	100 Medicare patients	100 Medicare patients
Price per injection	$50/injection	$1,950/injection
Monthly Expenditure	$5,000/month	$19,500/month
Reimbursement profit	$10/injection	$117/injection
ANNUAL PROFIT	**$12,000/year**	**$140,400/year**
Ophthalmologists prescribing Lucentis over Aventis profit approximately $128,400 more per year from Medicare reimbursement alone		

C. Stage 2: Defendants Promote the Profitability of a Direct Distribution Channel Over Purchases Through Distributors (2008-2018)

153. By 2008, it became clear to Genentech that, without more, neither its scare tactics nor appeals to Lucentis' raw reimbursement advantage would deter physicians from prescribing Avastin over Genentech's preferred product.

154. As Relator witnessed at Genentech's headquarters during this period, Genentech made the conscious business decision to provide physicians with greater financial inducements than the two products' Medicare Part B reimbursement spread offered alone. The vehicle for these greater inducements was Lucentis Direct, an alternative distribution channel through which customers could bypass distributors and purchase Lucentis from Genentech directly.

155. Lucentis Direct's marketing campaign would emphasize that customers' financial return on Lucentis purchases would far exceed those for Avastin due to the various forms of remuneration and practice support the physicians received. The program's ambitious purpose was not only to relieve customers of the financial burdens associated with purchasing Lucentis, but to make it highly profitable for them to do so in very large quantities.

156. When Lucentis Direct was in place, senior leadership including Mr. Snisarenko and Mr. Campbell routinely organized dinners with ophthalmologists running large-volume practices to discuss the revenue opportunities presented by Genentech's "new program." Relator

was made aware of all dinners at which one or more providers who fell within his region was present.

157. Genentech's marketing strategy for Lucentis Direct proved very effective. Between 2008 and approximately 2011, the program was successful in capturing a large segment of the wet AMD market. Additionally, Lucentis Direct converted hundreds of physicians and often entire ophthalmology practices from Avastin to Lucentis based solely on the latter's comparative revenue advantages.

158. Among the large retina practices whose Lucentis purchase volumes grew exponentially after the program's launch were Mid-Atlantic Retina in Pennsylvania (which later became Lucentis Direct's largest customer), and two of Relator's own customers, Vitreoretinal Surgery, PA ("VRS") in Minnesota, and Associated Retinal Consultants ("ARC") in Michigan.

159. In a typical example of a Lucentis Direct customer's purchasing volume, Dr. Jeffrey S. Rubin of the New York Eye and Ear Infirmary of Mount Sinai ordered nearly $30,000 in Lucentis in the three-week period between May 13, 2010 and June 4, 2010 alone.[8]

160. An internal Genentech document prepared within the first year of Lucentis Direct's launch noted that "[t]his channel was completed ahead of schedule in three months and now accounts for about 18% of all Lucentis sales." Ultimately Lucentis Direct would account for more than 75% of Genentech's sales of Lucentis.

[8] Genentech's June 11, 2010 invoice to Dr. Rubin identifies three $9,565 credit card orders, for a total balance of $28,695. The invoice further specifies that "[a]s a reminder, all credit card orders for LUCENTIS DIRECT orders will be charged 60 days from order date."

1. Lucentis Direct Builds Financial Inducements into Lucentis Direct to Overcome Avastin's Clinical Equivalence and Physicians' Practice Management Objections

161. Lucentis Direct's three core features were its direct distribution channel, its credit card program, and its rebate program.

a. Direct Distribution Channel

162. Between 2006 to 2008, it was only possible to purchase Lucentis through distributors. In its August 2007 business update, Genentech's Northwest Division includes among "common growth obstacles across the Division" that "physicians see distributor as unnecessary middleman."

163. Responding to this economic concern, Lucentis Direct eliminated the service fee charged to physicians by specialty distributors like Defendant MSH. Under Lucentis Direct, Genentech sold the product directly to ophthalmologists to avoid paying a 2% fee that would normally be paid to distributors for expenses such as shipping costs. Instead of the fee being paid by customers, distributors were paid the fee by Genentech. This cost reduction had the effect of lowering the product's price exclusively for Lucentis Direct customers.

164. Genentech's promotion of its "direct distribution channel" misleadingly implied that that it did not incur distribution costs through Lucentis Direct. In fact, Genentech did use and pay distribution service fees to distributors as part of the Lucentis Direct program, and yet provided those distribution services valued 2% per vial to Lucentis Direct customers free of charge.

b. Credit Card Program

165. Defendants understood that in order to address Lucentis' cash flow problem physicians would require Genentech to bankroll their use of credit cards with extended billing terms. Without more favorable billing terms than what distributors offered, physicians were confronted with a Hobson's choice between advancing hundreds of thousands of dollars while awaiting Medicare Part B reimbursement or paying distributors a 2% credit card transaction fee for every purchase.

166. In contrast, under Lucentis Direct, physicians were not only permitted but were *required* to purchase the product using credit cards, and directly from Genentech. When marketing the program, Genentech's sales team made physicians aware that its features would compare very favorably to those offered by traditional buy and bill arrangements with distributors. Those features had three key components.

167. First, where distributors had required physicians to pay in cash within 30 days of purchase or be charged a 2% credit card processing fee on all purchases, Defendants waived all credit card processing fees on Lucentis Direct credit card purchases.

168. Second, where distributors had required cash-paying physicians to pay within 30 days of purchase, Lucentis Direct offered physicians an extended 60 grace period for credit card payments. For maximum effect, Defendants even refrained from processing credit card purchases until 60 days after customers had ordered and received the drug. Together,

Genentech's 60-day grace period and the card's 30-day credit card billing period gave ophthalmologists 90 days of interest-free, charge-free credit card purchasing power.[9]

169. Third, building upon the credit card program's cash flow benefits, Lucentis Direct offered physicians the ability to collect 2% cash back or travel rewards on all Lucentis purchases. American Express, whose Black and Plum cards were used for Lucentis Direct accounts, commented that Genentech created more Amex Black Card users than any other vendor through Lucentis Direct credit card sales.

170. The credit card program was so lucrative to customers that, according to Campbell, members of Genentech's Executive team would personally advise large purchasers to arrange for their banks to hold and invest Medicare's reimbursements to generate a return while waiting out billing cycles.

c. Quarterly Rebate Program

171. When Eylea was launched in 2011, boasting better efficacy, less frequent patient injections, and a lower cost, Genentech responded by adding financial incentives to its Lucentis Direct program.

172. Where Lucentis Direct's earlier inducements had targeted the largest Avastin writers as a first priority, Defendants' quarterly rebate program was added to protect the largest Lucentis users from switching to Eylea when that product came to market.

173. Defendants designed their 2-3% back end volume and growth-based quarterly rebate specifically to compete with Eylea's improved efficacy over Lucentis. Genentech paid the

[9] Even when Genentech later shifted to a 30-day grace period, Genentech's FPMs coached physicians to order based on credit card billing cycles that had the effect of creating 60-day billing terms. For example, if the physician's credit card billing cycle date was May 14th, FPMs would coach the physician to order Lucentis on May 15th. Since Medicare would reimburse the physician for Lucentis by June 15th and Genentech would also not charge the Lucentis order until June 15th, the physician would have until July 15th to make the purchase.

quarterly rebate to physicians based on purchase volume, such that the more Lucentis they used and the more their purchases grew, the higher the rebate they would receive each quarter.

174. This rebate program allowed many physicians to remain Lucentis prescribers because the profit they realized was greater than they would earn with Eylea. Relator learned while employed at Genentech that many large offices were receiving rebate checks for greater than $100,000 per quarter.

175. For example, Mid Atlantic Retina Specialists received $500,000 rebate checks from Genentech that were as high as $60 million in Lucentis business per quarter. Mr. Campbell reported to Relator that, at a dinner with Dr. Carl Regillo, the primary physician with Mid Atlantic Retina Specialists, Dr. Regillo advised that their profit margin from Lucentis was as high as 11%. Dr. Regillo boasted that physicians received annual bonuses of $10 million as a result of the program.

2. Genentech's Franchise Program Manager Team Focuses Narrowly on Promoting Lucentis Direct's Profitability

176. Following Eylea's entry into the market in 2010, Genentech created a specialized sales team called Franchise Program Managers ("FPMs"), led by Mr. Campbell, whose sole responsibility was to promote the profitability of Lucentis Direct over that of purchasing treatments through distributors.

177. FPMs such as Amy Gutwald, Randy Gubler and Russ Ruspini were veteran Genentech sales representatives brought in by Mr. Campbell to act as Lucentis Direct consultants to doctor's offices. Regarded as a secret marketing weapon within Genentech, FPMs were referred to internally as "Ninjas" due to the aggressiveness of their financial sales messaging.

178. The FPM team worked with offices to manage the business side of buying and billing Lucentis, and to ensure that offices availed themselves of all of the program's features.

179. FPMs helped physicians manage the entire life cycle of a Lucentis Direct purchase from enrollment in the program to Medicare reimbursement. Mr. Campbell disclosed to Relator that there were business managers and sales representative whose sole responsibility was to teach physicians step by step on how to profit through Lucentis purchasing.

180. FPMs impressed upon providers that using Lucentis Direct could provide financial benefits that would outweigh any profit that could be gained from the use of competitor drugs Avastin and Eylea. In support of this proposition, FPMs would walk physicians through illustrative alternative revenue calculations, as further described below.

181. As user numbers increased, Genentech created the Local Market Unit ("LMU") to manage the largest users. The team included members of the CS, FRM and FPM teams, leadership, and marketing. The LMU managed and addressed any issues large-volume users experienced in ordering Lucentis.

3. Defendants' Illegal Kickback Violations Through Lucentis Direct

a. Defendants Marketed the Spread Between Lucentis Direct Purchases and Purchases Through Distributors

182. In violation of the AKS, Defendants illegally promoted Lucentis Direct's economic benefits over competing products in order to induce Medicare Part B reimbursements of the drug.

183. First, Defendants promoted the fact that Lucentis Direct allowed ophthalmologists to avoid paying a 2% per vial fee that distributors charge purchasers for shipping and related costs. From 2008 to 2018, Lucentis Direct customers' reduction in costs resulting from these

free distribution services, without any corresponding reduction in ASP, increased their Medicare reimbursement profit margin by 2% per vial.

184. Defendants let customers know that their receipt of these free services without it being reported as a discount caused Medicare to reimburse Lucentis to Genentech's customers at inflated rates.

185. Second, Genentech promoted the economic benefits of the Lucentis Direct credit card program to physicians. The program's credit card-based remuneration, including its credit card transaction fee waiver, cash back and travel rewards, and extended billing terms, was integral to the program's success. As an inducement to purchase Lucentis, customers were required to make all purchases using credit cards offering each of those benefits, and Defendants coached physicians on how manage their purchasing in a way that would extract the most value out of the program.

186. For example, FPMs aggressively coached physicians on how to use American Express "Black" and "Plum" cards, including marketing the cash back that physicians could gain when purchasing Lucentis. Black and Plum card cash back terms and other benefits were much more favorable than those for traditional AmEx cards. For example, the Plum card had the potential to double customers' purchase amounts as cash back, with no maximum limit.

187. FPMs also coached customers on how to take advantage of Lucentis Direct's billing terms, such that, for example, by the time a practice was required to pay $1,000,000 for a shipment of Lucentis vials, Medicare would have had already reimbursed $1,060,000 (ASP + 6%).

188. Third, from 2011 through 2018, Defendants promoted the economic value of an additional 1-3% quarterly rebate off of Lucentis' price, calculated based on the customer's purchasing volume and growth for the quarter.

189. Instead of referencing CMS's reimbursement metric of ASP + 6%, FPMs sold Lucentis Direct's reimbursement spread to doctors as Wholesale Acquisition Cost ("WAC") + 4.2%. Lucentis' WAC price, $1,950, represented the price Defendants charged distributors for their direct purchases, and did not incorporate any of the discounts or rebates referenced above that physicians received under the Lucentis Direct program.

190. By promoting Lucentis Direct's reimbursement spread of WAC + 4.2%, FPMs were able to highlight three bottom line profit drivers for prospective customers: (1) Medicare Part B reimbursement, inflated through Lucentis' unreported distribution fee discount; (2) up to 3% cash back on the AmEx Plum Card, free of credit card transaction fees; and (3) up to 3% quarterly rebate based on volume and growth.

191. The following is an example of a marketing pitch that FPMs would present directly to physicians to describe how Lucentis Direct's three profit drivers could generate revenue for their practices:

Profit Drivers	**Revenue Per Injection**
Medicare Part B ($1,950 + 4.2%)	$81.90
3% Cash Back	$58.50
3% Quarterly Rebate	$58.50
Total Profit Per Injection	$198.90
Ophthalmology practices that utilize 1,000 vials per month generate $198,900 in profits per month and $2,386,800 in profits per year when purchasing through Lucentis Direct	

b. Defendants Failed to Include Lucentis Direct Program's Free Distribution Services in Lucentis' Reported ASP

192. The cost of Defendants' free distribution services was not included in Lucentis' reported ASP but should have been. In a July 2008 "Ophthalmology Times" article, then Sales and Marketing VP Snisarenko publicly acknowledged the value that its distribution services offered to physicians: "What we're offering is a live call center and the ability to ship to multiple addresses . . . . Physicians have been asking to speak directly with Genentech." *Genentech reinvigorates vision as biotech resource for patients, physicians*, Ophthalmology Times (July 15, 2008), https://www.ophthalmologytimes.com/article/genentech-reinvigorates-vision-biotech-resource-patients-physicians.

193. The article further reports that Lucentis Direct "does not replace wholesale distributors," suggesting that those distributors continued to charge a distribution fee for shipments made to Lucentis Direct customers. *Id.*

194. Defendants' knowledge that they were required to report the distribution service fee as part of ASP is evidenced by their conduct involving a similar 2% discount that went unreported during the first three years Lucentis Direct was in operation.

195. As was true with respect to the distribution fee throughout the program, Lucentis Direct customers were never charged the 2% credit card service fee described above. Between 2008 and 2011, however, customers derived an even greater windfall profits as the 2% discount was not reported as part of Lucentis' ASP during that period.

196. During that period, Genentech wrote off this discount as a marketing expense rather than reporting it to the Government. However, Genentech corporate management became concerned about the legality of paying the credit card fee without reporting it as a rebate. As part

of a 2011 compliance review, Genentech internally determined that the fee waiver had lowered Lucentis' purchase price for Lucentis Direct customers and should have been reported as such. Thereafter, Genentech reported the fee waiver as a rebate that lowered Lucentis' ASP, arguably bringing it under the protection of the Discount Safe Harbor.

D. Stage Three: Defendants Promote the Profitability of Purchasing Lucentis Through an Exclusive Group Purchasing Organization Over Buy & Bill Purchasing (2018 to Present)

1. Lucentis Direct's Failure to Sustain the Drug's Profitability Over Its Competitors Compels Defendants to Restructure the Program

197. While the drug enjoyed its heyday during the early Lucentis Direct years, Lucentis' perceived clinical inferiority to Aventis, Eylea and, most recently Beovu, has caused its market share to decline steadily in the eight years since Eylea's launch.

198. By 2017, the detrimental effects of competition, combined with the looming June 2020 expiration of Lucentis' United States patent, have compelled Defendants to pursue an updated, eleventh-hour illegal inducement scheme designed to extract as much remaining profit as possible from their declining product.

199. First, Lucentis Direct's successful conversion of many Avastin prescribers to Lucentis could not prevent the medical community overall to embrace off-label use of Avastin to treat AMD. Defendants' subterfuge concerning Avastin's purported safety risks could only last as long as they could continue to thwart the medical community's efforts to secure an FDA-approved AMD indication for Avastin. But, even short of approval, the NIH's 2012 release of the CATT study results sounded the death knell of this marketing approach, with data showing

that bevacizumab is both safe and effective for the treatment of AMD and non-inferior to Lucentis.

200. As a result, off-label use of the drug accounts for a substantial percentage of the AMD market by volume. Thus, even though Avastin's high-volume utilization does not have a material impact on Lucentis' market share given its low price, Avastin's reputation as the financial equivalent of a generic substitute to Lucentis harmed the franchise.

201. Second, Lucentis sales had not recovered from losses caused by Genentech's reporting of the credit card discount as back end quarterly rebates reducing the drug's ASP. Instead of dissuading physicians from prescribing Eylea, the reporting of these rebates lowered customers' reimbursement rate and decreased Lucentis sales overall. Combined with patients' preference for Eylea's less frequent dosing requirements, this reporting caused Lucentis to dramatically lose market share to Eylea.

202. Third, by 2018 it became clear that Beovu would likely be approved for nAMD, and that Lucentis would be relegated to playing third fiddle behind Eylea and Beovu. Beovu' s October 2019 approval all but ensured that Lucentis' competitors would seize its market share for the duration of its patent protection, and thereafter. Defendants understood that physicians were unlikely to defect to Beovu until it was assigned a J-Code guaranteeing Medicare reimbursement, an approximately one-year process. This gave Defendants more time to implement their new scheme.

203. Finally, Genentech's corporate management, including Marketing Vice President Chris Simms, had long been concerned by the perception that Lucentis Direct gave too much preferential treatment to customers participating in the program.

204. Anticipating that the Lucentis Direct model would neither offer physicians a competitive economic benefit any longer, nor shield Defendants from fraud and abuse enforcement scrutiny any longer, Genentech opted to reconfigure and expand upon Lucentis Direct's incentives by offering the product through a GPO.

2. Defendants Remake Lucentis Direct's Inducement Scheme as a Sole-Source Group Purchasing Organization

205. Responding to these concerns, in 2018, Genentech and its distributor, McKesson, replaced Lucentis Direct with Defendant Onmark. Through Onmark, Genentech's Lucentis Direct customers transitioned into a Group Purchasing Organization ("GPO") run by Onmark.

206. Under the Defendants' arrangement with Defendants McKesson, MSH and Onmark, Genentech was granted a lucrative sole-source contract, under which the Company was granted the exclusive right to sell its AMD product, Lucentis, through the Lucentis GPO.

207. Also central to Defendants' arrangement is the requirement that customers seeking to continue their Lucentis Direct benefits must become Lucentis GPO members and to sign distribution contracts with Defendant McKesson. By 2018, more than 1,000 retina specialists purchased Lucentis through Onmark's Lucentis GPO.

a. Onmark Restores Lucentis Direct's pre-2011 Inducements

208. Onmark's Lucentis GPO is merely a subterfuge designed to revert to the more profitable incarnation of Lucentis Direct that existed prior to Genentech's reporting of the credit card fee discount as a rebate. Under Onmark, Genentech markets the spread between what revenue customers will generate when making Lucentis purchases through the GPO against what revenue they would generate were they to seek reimbursement for Lucentis, or any other product, directly from Medicare.

209. Onmark's GPO structure enables Defendants to extend all of Lucentis Direct's present and former inducements without Genentech having to pay them directly. In particular, the structure enables Genentech to conceal both of Lucentis Direct's previously reported discounts under the guise of a legitimate GPO. To accomplish this, Defendants knowingly pass the distribution fee discount (2%) and the credit card fee discount (2%) described above through service providers and Defendants McKesson and Onmark.

210. Genentech pays Onmark and McKesson up to 4% in service fees, while Defendants Genentech and Roche pass up to 4% in discounts to Lucentis customers through Defendants McKesson, MSH and Onmark. Pass-throughs received by Onmark GPO customers range from 1% to 4%, based on growth and volume.

211. Like Lucentis Direct customers, Onmark members are not required to pay a distribution fee, nor is Lucentis' ASP lowered by virtue of the discount. Defendants have also restored the 2% unreported credit card fee discount that they had reversed in 2011 due to compliance concerns. All of Lucentis Direct's cash back and other inducements remain in place as well. The highest level of pass-through discount was the Lucentis GPO "Super-Tier," which gave physicians 3-4% in front-end discounts not deducted from ASP.

b. Lucentis GPO Account Managers Focus on Maintaining Legacy Accounts Rather Than Attracting New Prescribers

212. As part of Lucentis Direct's conversion to Onmark, Genentech eliminated its entire sales force, including the FPMs who had been selling on the front lines of that program. Defendants knew that the competitive landscape and Lucentis' impending patent expiration required them to try to maintain Lucentis' existing customer base for as long as possible. To that

end, Genentech created an "Account Management" department that would be instructed to call only on existing Lucentis Direct customers targeted for conversion to Onmark.

213. The primary function of Genentech's Onmark Account Managers was to transition Lucentis Direct customers to the new program and then to manage those customers' ophthalmology businesses. A smaller team was tasked with moving Eylea and Avastin users to Lucentis.

214. Defendants' "Genentech Access to Care" ("GTATC") program offered additional support services for Onmark's Lucentis Direct recruits, including prior authorization support, appeal support, and patient assistance programs.

3. Defendants' Kickback Violations Through the Lucentis GPO (2018-Present)

215. Onmark's function in the Lucentis franchise is to engage in transactions that Genentech cannot engage in directly, while appearing to comply with the AKS. In order to achieve this, Defendants' distribution and GPO arrangements were designed to create the false appearance of safe harbor protection.

a. Defendants Marketed the Spread Between the Lucentis GPO and Medicare Reimbursement

216. Upon switching to the Lucentis GPO distribution model in 2018, Genentech began promoting its Lucentis GPO "Super-Tier" for its highest-level prescribers. As described above, this "Super-Tier" gave physicians 3-4% in front-end discounts not deducted from ASP.

217. As part of its Onmark GPO marketing campaign, Genentech sales representatives tell customers that Onmark's 7% in price reductions—4% in unreported discounts and 3% in reported rebates—along with the other benefits carried over from Lucentis Direct, offer a greater

net profit than those offered by Regeneron for Eylea, for which Eylea's comparable discounts were limited to only 3%.

218. Genentech sales representatives are instructed to make the economic case for Onmark membership to physicians in its purest form. The Company's talking points include statements such as GPO membership is so economical that it offers to "take the clinical decision" and the "reimbursement decision" "out of the physician's hands."

219. Genentech was motivated to aggressively promote the perks of Lucentis in this way because they knew that Lucentis would soon be a distant third behind Beovu and Eylea in the increasingly crowded nAMD market.

220. Novartis sales representatives including David Kaplan and Mike Winship report that Genentech's aggressive efforts have been successful. For example, Dr. Phil Ferrone of Vitreoretinal Consultants ("VRC") stated to a Novartis representative that VRC will not use Beovu until Novartis "changes its business model" to match or improve upon the financial rewards VRC receives through Onmark membership.

221. From 2018 to the present, Genentech has also continued to promote the economic benefits of the Lucentis Direct credit card program. That program's fee waivers and cash back remuneration remain in play as physicians may continue to use their credit cards to purchase Lucentis through the Lucentis GPO.

b. Genentech's 4% Administrative and Distribution Fees Paid to Onmark and McKesson Are Not Bona Fide Service Fees, but Price Concessions That Should Be Included in Lucentis' ASP

222. Genentech has long been aware of how discounts paid to customers could be insulated from AKS scrutiny when made though GPOs. In February 2007, Genentech lobbied

CMS to prevent it from treating GPO discounts as price concessions even when they did not qualify as *bona fide* service fees. In a letter written to CMS Acting Administrator Leslie Norwalk on February 20, 2007, Genentech's Vice President of Government Affairs Walter Moore wrote:

> Genentech is of the view that administrative fees paid to GPOs do not constitute price concessions . . . . We hope [CMS's] Final Rule will confirm our position and, for the sake of clarity, also stipulate that GPO fees need not satisfy the *bona fide* service fee exception . . . . GPO members are not required to, but rather are merely permitted, at their own discretion, to purchase drugs under the contracts the GPO has negotiated . . . . [B]ecause GPOs are both non-purchasers and non-payers, fees paid to them cannot be said to reduce the drug prices available to manufacturers to buying group members.

February 20, 2007 Letter from Walter Moore to Leslie Norwalk, at 15 (emphasis retained from original).

223. Nearly a dozen years later, Genentech structured an arrangement that violated the very same standards it opposed at the regulatory level. Under the arrangement, Genentech pays GPO Onmark and Specialty Distributor McKesson a combined GPO administrative fee and distribution fee of 4% per transaction. These discounts are passed through to Onmark customers within a range of 1-4 % based on the growth and volume of the customers' Lucentis sales.

224. As was true for Lucentis Direct customers, Onmark members are not required to pay the 2% distribution fee they would be charged were they to purchase Lucentis or any other AMD product outside of Lucentis Direct or Onmark. Instead, Genentech pays those fees to Defendant McKesson without customers incurring any expense, whether through Lucentis' ASP or otherwise.

225. McKesson's distribution arm necessarily receives at least 1% of Genentech's 4% price reduction, as Onmark may lawfully receive a maximum of 3% in administrative fees from a manufacturer under the GPO safe harbor without the manufacturer having to report the discount as part of ASP. In this way, Onmark customers and receive the same free and unreported

distribution services that Lucentis Direct customers before them received, albeit in the form of a "pass through" discount ostensibly protected by relevant AKS safe harbors.

226. Discounts extended by GPOs to their members using administrative fees received from manufacturers are generally protected by the "*bona fide* service fee" ("BFSF") safe harbor for purposes of Genentech's ASP calculations and submissions to CMS. *See* 42 C.F.R. § 414.802, *supra*. Insofar as the 1-4% tiered discount paid by the GPO to its members falls within the BFSF safe harbor, Genentech is not required to report the discount as part of ASP.

227. Insofar as the 1-4% tiered discount paid by McKesson to the Onmark physicians to whom it ships Lucentis falls within the BFSF safe harbor, then neither is Genentech required to lower ASP by the amount of that discount.

228. OIG Guidance and the relevant Final Rule provide that, when directed by a manufacturer, such a "pass through" violates the *bona fide* service fee safe harbor and must be reported as a discount. A manufacturer's knowledge of or involvement in a vendor's passing through of fees to its customers triggers that manufacturer's obligation to report the fees as part of ASP.

229. OIG Guidance allows manufacturers to presume that a fee is not passed on "in the absence of evidence or notice to the contrary. Here, however, Defendants' 4% pass through discount paid to Onmark members was conceived of by the manufacturer itself, as a substitute for illegal discounts structured differently under Lucentis Direct.

230. Genentech's distribution service fees to McKesson are routinely passed through to McKesson's physician customers with Genentech's knowledge. Such pass-throughs disqualify the distribution fees paid to McKesson as *bona fide* service fees and require Genentech to report the fees as discounts on ASP, which it failed to do.

231. Likewise, Genentech's GPO administrative service fees to Onmark are routinely passed through to Onmark's physician customers with Genentech's knowledge. Such pass-throughs disqualify the administrative fees paid to Onmark as *bona fide* service fees and require Genentech to report the fees as discounts on ASP. Genentech knowingly and willfully fails to lower Lucentis' ASP for any portion of the 1-4% tiered discount, whether attributable to the GPO pass-through or the distributor pass-through.

232. In a 2018 advertisement to prospective GPO members, Onmark states that "[i]n addition to Genentech's direct discounts and rebates on Lucentis, Onmark members can achieve up to an additional 2% rebate on their quarterly purchases." Onmark's 2018 advertisement also states that "[w]e have delivered more than [$11 million] in Lucentis rebates to Onmark GPO members."

233. Onmark's advertisement is consistent with Genentech's promotional message to customers that GPO membership offers the same benefits as those of Lucentis Direct, plus the additional 2% unreported discount that was available to customers during the early years of that program. The Onmark advertisement's reference to Genentech's "direct discounts" appears to be a tacit reference to Lucentis Direct's financial inducements, designed to ensure that Lucentis customers remain so for the product's duration on the market.

VII. CAUSES OF ACTION

COUNT I

Federal False Claims Act— Violations for Causing Submission of False Claims to the United States U.S.C. § 3729(a)(1)(A)

234. Relator realleges and incorporates by reference the allegations in all previous paragraphs of this Complaint.

235. Relator seeks relief against Defendants under Section 3729(a)(1)(A) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

236. As described above, Defendants have knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729(a)(1)(A).

237. As a result of these false claims, the United States has been damaged in a substantial amount and continues to be damaged, in an amount yet to be determined.

238. Additionally, the United States is entitled to the maximum penalty of $21,562.80 for each and every false and fraudulent claim made and caused to be made by Defendants and arising from its fraudulent conduct as described herein.

COUNT II
Federal False Claims Act –
Violations for Causing Submission of False Claims to the United States
U.S.C. § 3729(a)(1)(B)

239. Relator realleges and incorporates by reference the allegations in all previous paragraphs of this Complaint.

240. Relator seeks relief against Defendants under Section 3729(a)(1)(B) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

241. As described above, Defendants have knowingly made, used, or caused to be made or used false records and statements material to false or fraudulent claims paid or approved by the United States, in violation of 31 U.S.C. § 3729(a)(1)(B).

242. As a result of these false claims, the United States has been damaged in a substantial amount and continues to be damaged, in an amount yet to be determined.

243. Additionally, the United States is entitled to the maximum penalty of $21,562.80 for each and every false and fraudulent claim made and caused to be made by Defendants and arising from its fraudulent conduct as described herein.

COUNT III
Violations of the False Claims Act – Conspiracy
31 U.S.C. § 3729(a)(1)(C)

244. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

245. Relator seeks relief against the Defendants under Section 3729(a)(1)(C) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

246. As set forth above, Defendants have conspired with their officers, agents, and employees to defraud the United States Government by presenting false or fraudulent claims for payment in violation of 31 U.S.C. § 3729(a)(1)(C).

247. Defendants conspired together with their officers, agents, and employees authorizing them to take and conceal the actions set forth above.

248. As set forth in the preceding paragraphs, Defendants have knowingly violated 31 U.S.C. § 3729(a)(1)(C) and have thereby damaged the United States Government by their actions in an amount to be determined at trial.

VIII. PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Defendants, ordering that:

A. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. §§ 3729-33, as amended;

B. Defendants pay not less than $10,781.40 and not more than $21,562.80, as adjusted by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (28

U.S.C. § 2461), plus three times the amount of damages the United States has sustained because of their actions;

C. Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and the equivalent provisions of the State False Claims Acts set forth above;

D. Relator be awarded all costs of this action, including attorneys' fees and expenses pursuant to 31 U.S.C. § 3730(d); and

E. The United States and Relator be awarded such other relief as the Court deems just and proper.

IX. DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues triable of right by jury.

Dated: January 24, 2020

Respectfully submitted,

/s/ Timothy Schofield
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